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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,483	07/10/2000	Jennie P. Mather	145072000110	1943

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EXAMINER
JAMROZ, MARGARET E

ART UNIT	PAPER NUMBER
1644	14

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/614,483	Applicant(s) MATHER ET AL.	
	Examiner Margaret E Jamroz	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 29-57* is/are pending in the application.

4a) Of the above claim(s) *7,14,15,22,29,30,37,43,44 and 48-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-13,16-21,23,31-36,38-42 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-23 and 29-57 are pending.

2. Applicant's election with traverse of Group II (claims 11-23 and 31-47) in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the methods encompassed by Group II are classified in the same class as claim 1. Groups I and II have been re-joined. The restriction between claims 11-23 and 31-47 and Groups III and IV is still proper.

The requirement is still deemed proper and is therefore made FINAL.

Applicant further elects species of biological substrate, cells of embryonic origin, and ELISA or immunoblot. Claims 1-6, 8-13, 6-21, 23, 31-36, 38-42, and 45-47 read on the elected species. Upon further consideration, the prior art search has been extended to cover cells of adult origin.

Claims 7, 14-15, 22, 37, and 43-44 (non-elected species of elected Groups I and II) and claims 29-30 and 48-57 (non-elected Groups III and IV) are withdrawn from further consideration by the 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions.

Claims 1-6, 8-13, 16-21, 23, 31-36, 38-42, and 45-47 are under consideration in the instant application.

3. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

5. The disclosure is objected to because of the following informalities:

The use of the trademarks "GenBank" and "SWISS-PROT" have been noted in this application on page 19, paragraph 2. It should be accompanied by the ® symbol wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required.

6. The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Specifically, the "a" in inventor Jeannie Mather's name was crossed-out; and the country of citizenship for inventor Jean-Philippe F. Stephan has been changed.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 10 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The terms "ASC, ESC, ROG, BUD, RED, NODD, BR516, RL-65, and NEP" in claims 10 and 40 are relative terms which renders the claim indefinite. The terms "ASC, ESC, ROG, BUD, RED, NODD, BR516, RL-65, and NEP" are not defined by the claim, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant should include the full name of each cell line followed by its appropriate abbreviation in parenthesis.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 10 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that ASC, ESC, ROG, BUD, RED, NODD, BR516, RL-65, and NEP cell lines are required to practice the claimed invention.

The reproduction of the cells from the disclosed sources is an unpredictable event. The cells, disclosed on page 13 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the cells, and it is not apparent if the cells are readily available to the public. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines. See 37 CFR 1.801-1.809.

If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the cells have been deposited under the Budapest Treaty and that the cells will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit, 5 years after the last request for a sample, or for the enforceable life of the patent whichever is longer. See 37 CFR 1.806.

If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the cells described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-6, 8-13, 16-21, 23, 31-36, 38-42, and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,932,704, in view of U.S. Patent 5,714,385.

The '704 patent teaches a method of making monoclonal antibodies against a cell surface receptor. A collection of monoclonal antibodies were generated by immunizing mice with viable adult human cells (e.g. heterologous) expressing cell surface antigens (see column 3, paragraph 3 in particular). Hybridomas were produced by fusing splenocytes with SP2/0 myeloma cells (i.e. immortalized cells) to produce monoclonal antibodies. The resulting supernatants were tested for antibody production by ELISA (i.e. an immunoassay; see column 4 in particular).

The '704 patent does not specifically teach culturing cells in serum-free media (claims 2, 17, and 32), growing cells on a biological substrate (claims 5-6, 20-21, and 35-36), cells of an ectodermal, endodermal, or mesodermal origin (claims 9 and 39), or using cells of embryonic origin, such as ESC and adult cells, such as ASC (claims 8, 23, and 38).

The '385 patent teaches a method for enhancing the survival and/or proliferation of human adult (ASC) and embryonic Schwann cells (ESC) by culturing the cells in serum-free media on a biological substrate (i.e. laminin; see Figs 4A-4B; column 7, lines 23-34; column 18, paragraph 1; column 30, (i) Primary culture; and column 32, (iv) growth factor studies in particular). The ESC were generated from rat dorsal root ganglia are of ectodermal origin. The '385 patent further teaches monoclonal antibodies directed toward antigen can be produced by any method which provides for the production of antibody molecules by continuous cell lines in culture (see column 10, paragraph 2 in particular).

The growth of cells in a monolayer or aggregate is an inherent property of the cells.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the human adult (ASC) or embryonic Schwann cells (ESC) grown in serum-free media on a biological substrate taught by the '385 patent in the teachings of the '704 patent to have a method for producing a population of monoclonal antibodies reactive against cell surface antigens.

One of ordinary skill in the art would have been motivated to do this because the cells grown in serum-free media in the '385 patent have increased viability and proliferation, and the cells taught in the '704 patent used for immunization were viable and expressed high levels of receptor. Therefore, one of ordinary skill would have a reasonable expectation of success that the viable ASC and ESC cells could be utilized to immunize a heterologous animal to generate a collection of monoclonal antibodies.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
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Technology Center 1600
January 11, 2002

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